BBMG-100US PATENT

## **Remarks/Arguments:**

By this preliminary amendment, claims 1 and 2-10, the specification, the drawing, and the abstract have all been amended to place the application in better condition for examination and allowance. Claims 11-20 have been added to secure enhanced protection for the applicants' invention. Entry of this preliminary amendment and issuance of a first action on the merits are requested.

Respectfully submitted,

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Attachments: Substitute Specification (with and without revision marks);

Figure 1 (1 sheet);

Abstract

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Kathleen Libby

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## SUBSTITUTE SPECIFICATION WITH REVISION MARKS

# **DIALYSIS STATION**

#### BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to a dialysis station with at least one patient place and a central server.

# Description of Related Art

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A station with several patient places for the extracorporeal blood treatment is disclosed in International Patent WO 02/069793 A2. This blood treatment system comprises several blood treatment apparatus each of which is provided with a video terminal. Each of the video terminals, configured as touch screens, forms an input/output unit via-by which the operating personnel is able to input data into the respective blood treatment apparatus. In such cases, no central server is necessary which would be necessary otherwise. The operator may also input information on possible occurrences or the condition of the patient at the video

terminal. The video terminals are linked among each other and with the server to form an internal network. Other video terminals which are not allocated to a special patient place may also be connected to this internal network. These decentralized stations form independent communication units. The server includes a patient management system in which patient data and the treatment history are stored.

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#### SUMMARY OF THE INVENTION

It an the object of the present invention to provide a dialysis station comprising a central server and at least one patient place, where it is not only possible to monitor the treatment at each patient place from a physician place but also to intervene into this treatment, and where a dialogue between the physician place and the patient place is possible via the data network.

This object is solved, achieved by providing a dialysis station according to the invention, by the features of claim 1. Specifically, The dialysis station according to the invention comprises at least one patient place having a dialyzer and a video terminal allocated thereto, a central server including a data base with a patient data file and an operational data and status data file of the individual dialyzers, and a physician place equipped with at least one video terminal, the video terminals and the server being interlinked with each other and configured such that information on the treatment course at a selected patient place are callable can be called at the physician place and that instructions and operational parameters for a selected patient place are adapted to be input at the physician place. An acknowledgment of the execution of an instruction is made in that the executing person acknowledges his or her identity.

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According to the invention, the acknowledgment of the identity is an acknowledgment of the execution of an instruction at the same time and is preferably stored. In a way, this acknowledgment has the function of a signature.

The dialysis station according to the invention permits to identify identification of the person making adjustments at the patient place, these adjustments being able to be made on the basis of an instruction of the physician at a remote place. Thus, there is an additional check that a certain instruction has been executed at a patient at the correct patient place - and thus at the intended patient. In the case of an instruction, this instruction is executed first and, subsequently, the executing person is identified on the basis of a password, a chip card, a magnetic card, and the like. The accepted acknowledgment of the identification simultaneously goes along with the report on the execution of the instruction to the physician place.

In dialysis, there is <u>an\_increasingly the</u> obligation to keep a record of all measures performed. \_A group of nursing personnel is always in charge of a certain group of patients. \_Therefore, it is important that instructions are executed at precisely that patient place for which they are intended. \_The invention permits an acknowledgment of the definite allocation of an instruction to a patient place. \_The acknowledgment of the identity of the executing person can be effected in that the person presses an "OK" key after he or she has input a password or an ID number. It may also be effected by reading in a data carrier carrying an ID identification into the machine.\_ In this case, no OK key is required.

The dialysis station according to the invention permits a bidirectional data communication between the physician place and each patient place. \_It is possible to directly intervene into the operation of each respective dialyzer from the video terminal of the physician place, and the operational parameters of the dialyzer can be changed by the physician. \_The operational parameters can be displayed and changed at the video terminal of the patient place as well, the change, if necessary, requiring a special authorization of the respective person and being registered in the system.

All patient-related data and all machine-related data of a patient place which can be displayed at the video terminal of the physician place can also be displayed at the video terminal of the respective patient place. \_The video terminal of the physician place can be switched to any of the patient places. \_The video terminal of a patient place, however, only shows the data of the dialyzer of this patient place and the respective patient. \_Only these data can be changed at the patient place.

The operational parameters set for a patient are either data pre\_stored

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in the server or data read out from a chip card of the patient or data calculated from certain measured values, e.g., the weight of the patient, or data taken-carried over from the last treatment. Inputting operational parameters requires the subsequent input of an ID identification of the executing person. The identity of the inputting person as well as the time of input is-are stored in the computer together with the respective instruction. It may also be provided that the instruction given by the physician has to be provided with an ID identification of the physician and acknowledged before this instruction is transferred to the patient place. In this case,

the instruction of the physician is stored along with the ID identification.

The central server includes a patient data file with the master data of the patient and information on particular sensitivities or tolerances as well as the operational and status data file of the individual dialyzers. \_Thus, it can be detected, for example, that a particular patient is only allowed to be treated at a certain type of dialyzer. \_The operational and status data file of the dialyzers also receives the operational parameters to be set for a patient.

The invention permits that a physician to supervises a selected dialysis from the physician place and actively intervenes into this dialysis. \_The intervention may be effected in that machine parameters are changed or that a particular medication is prescribed that has to be manually administered by the nurse at the patient place. \_The prescription of the medication as well as the reply or acknowledgment of the execution of the respective instruction is effected via the data network.\_ Subsequently, the dose of the medication is stored in the server along with the point of-in\_time. \_The server contains the history of each individual dialysis. Therefore, it also forms a documentation device.

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The video terminals of the patient places, of the physician place, and the server may be connected with each other to form an internal network, e.g., by a bus data system. \_The internal network, however, may also be connected to an external network. \_Thus, a physician place from the external network is able to communicate with each patient place. \_Thus, the physical presence of the physician in the dialysis station is not required.

By the term <u>"video terminal,"</u> an input/output station is to be understood which has a display and is prepared for the processing of data.

Preferably, it is a PC. \_The video terminal may also comprise a touch screen at which instructions and data can be input by touching certain fields. \_In this case, it can be done without a keyboard or a mouse.

At the patient place, an ID input device is provided for the identification of -patients and/or personnel. \_Such an input device is, e.g., a chip\_reading apparatus into which the chip card of a patient is input. \_The chip card includes certain patient data and patient information. \_These are transferred to the server which then transmits the related information from the patient data file to the video terminal of the patient place. \_Thus, a distinctive allocation of the patient to the respective dialyzer is effected.

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It is also possible to allocate an identification code to each operating person, which has to be input into a keyboard.

# BRIEF DESCRIPTION OF THE DRAWINGS

Hereinafter, embodiments of the invention will be explained in detail with reference to the drawings, in which:

- Fig. 1 is a schematic block diagram of the dialysis station according to the present invention,
  - Fig. 2 is a screen surface for inputting patient data,
  - Fig. 3 is a screen surface with a checklist for a selected patient,

Fig. 4 is a screen surface where the medication of the respective patient is indicated,

- Fig. 5 is a screen surface with curves of the arterial blood pressure, the venous blood pressure, and the trans\_membrane pressure in over the course of time,
- Fig. 6 shows a screen surface for the communication between physician -and operating personnel,

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- Fig. 7 shows a screen surface with a medication list,
- Fig. 8 shows a screen surface with an instruction list,
- Fig. 9 shows a screen surface with a personnel list, and
- Fig. 10 shows a screen surface for the password input.

### DETAILED DESCRIPTION OF THE INVENTION

In Fig\_ure 1, a dialysis station with several patient places 10 is illustrated. \_Each patient place 10 is provided with a corresponding bed or chair 11 as well as with a dialyzer 12. \_The dialyzer 12 is a dialysis machine connected with the patient's body via a hose system 13 and including, inter alia, a blood pump 14.

The dialyzer 12 is provided with a video terminal 16 comprising a touch screen forming an input/output device for a (non-illustrated) PC operatively connected with the controlling and measuring system of the dialyzer. The dialyzers

12 and the video terminals 16, respectively, are connected with each other and with a central server 20 via a data bus line 17 in order to form an internal network 21. Further, electronic scales 22 for weighing -the patient as well as a video terminal 23 arranged at a central physician place 24 are connected with the network 21. \_A further video terminal 25 may be arranged at an external physician place 26 connected with the internal network 21 by an external network 27. \_Thus, there is an additional access to the internal network 21 from a remote location.

The server 20 contains a data base and performs the entire management of all machine and patient data.

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The dialyzer 12 has a reading apparatus 18. \_It is a chip card reader for reading out data from a chip mounted on a chip card. \_The chip card serves to identify the operating person and the patient. \_By reading the chip card, the operating person and the patient are distinctly allocated to the respective dialyzer.

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Such a reading apparatus <u>18</u> is included in all the apparatus provided for the treatment of the patients, e.g., the scales 22 or laboratory apparatus as well.

The documentation and storage of patient data not measured by the dialyzer 12 is not effected on paper but exclusively in one of the connected computers, i.e., either in the computer of the patient place 10 or the physician place 24,26. \_Such patient data include the medication, indications on the well-being, and laboratory values.\_ The documentation of patient data during the treatment is always effected at the patient place 10. \_The patient information is put to the disposal of the server 20 and the respective physician place 24,26. \_Instructions to the operating personnel are sent from the physician place 24,26 to the patient place 10. \_The

respective video terminal draws the attention of the patient or the personnel to the arrival of a respective instruction by an alarm. \_Following the instruction has to be acknowledged by the personnel.

Fig.ure 2 shows a session mask as screen surface. In the field 30, the name and date of birth of the patient as well as the date of session and the present time are listed. Below, different information on the session have to be entered into respective fields 31.

Fig.ure 3 shows a checklist in the form of a screen surface. \_Under the category "Entry,", the checklist includes a number of activities that have to be carried out by the personnel in connection with a session. \_The execution of the activity is acknowledged by checking off under the category "Status.".

Fig.ure 4 shows a screen surface with the title "Medication." - The medicines to be administered to the patient are listed therein. \_Under the category "Date/Time" the intended time appears before the medicine will be administered; and after it has been administered, the execution time appears.

Generally, the medication instruction is prescribed by the physician. The physician may enter it at the physician places 24 and 26, respectively. \_As a basis for the medication, the physician has patient-specific parameters at his disposal, like those illustrated in the trend view of Fig\_ure 5, for example.

In Fig.ure 5, the upper curve 35 indicates the course of the transmembrane pressure TMP of the dialyzer over time, the central curve 36 the course of the venous blood pressure over time, and the lower curve 37 the course of

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the arterial blood pressure over time during a session of a patient. These values are detected at specified intervals and stored in the server 20. The physician is able to specifically call the respective curves and other information onto his video terminal to set the medication accordingly.

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Fig.ure 6 shows a screen mask with different symbols (icons) for the video terminal 16 of the patient place 10. \_Symbol 40 means the existence of a treatment instruction, i.e., an instruction to the personnel to execute certain instructions. \_The symbols are configured as switching surfaces of a touch screen. Symbol 41 indicates the existence of a medication instruction. \_If this switching surface is touched, the medication instruction appears. \_Symbol 42 means a request to the personnel to make an identification, i.e., to enter an ID number or the name.

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Fig\_ure 7 shows the medication instruction appearing in Fig. 6 after the symbol 41 has been touched. \_Upon touching, the arrow symbols 44 respectively open the complete text. \_The symbols in column 45 indicate the state of the medication, e.g.: due (asterisk), executed (check), and not due yet (exclamation mark in triangle). \_The medication list is prescribed and changed from the physician place 24,26. \_At the patient place \_10, it can only be changed after a corresponding identification of the physician. \_The name of the physician making an entry is also taken up into the medication list.

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In Fig. ure 8, the instruction list (list of treatment instructions) is illustrated which appears after touching the symbol 40 in Fig. 6. \_This list, e.g., includes the times at which a certain treatment at the patient has to be performed, e.g., "measuring the body temperature." -\_ After an instruction of the list has been

executed, this is acknowledged by the operating person by pressing an acknowledgment key 50 provided at the apparatus as a hardware key.

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Figures. 9 and 10 show the screen surface for the subsequent password entry of the personnel. \_First, the personnel list with the names of the respective nurses appears. \_The respective nurse may select and touch her name and acknowledge it by pressing the OK key 50. \_Thereafter, the alphanumeric keyboard illustrated in Fig.ure 10 appears. \_The nurse can input her ID number or a password thereinto. \_This is acknowledged by the OK key 52. \_Thereupon, the nurse is identified. \_Pressing the OK key 52 is the acknowledgment of the execution of the instruction at the place of work. \_With this variant, the screen mask illustrated in Fig. 10 forms the ID input device 18a for identifying the personnel.

Hereinafter, an example of a treatment course is indicated:

- 1. The patient enters into the dialysis center and identifies himself with an identification card at the scales 22. The patient weight is compared with the nominal weight and the difference is stored as nominal ultrafiltration for the following treatment.
- 2. The patient goes to any patient place 10 at all and identifies himself with his card there again. \_The apparatus automatically begins to prepare itself. \_From the data base of the server 20, the dialyzer settings and data desired for this patient are loaded, e.g., UF quantity, UF rate, blood pump speed, dialysate conductivity, \_\_\_\_and the like. These data have either been calculated (from the weighed weight), input by the physician or another authorized person, or taken carried\_over from the last treatment.

- 3. The patient is connected 7; the apparatus data transferred are used for the dialysis.
  - 4a. The nurse in charge also identifies herself at the dialyzer.
- 4b. During the dialysis, problems occur that require the apparatus parameters to be changed. \_The apparatus parameters are input. \_Together with the code of the person who has made the change, the new data are stored in the data base.
- 5. Actions at the patient and information on the patient—'s condition are- also documented at the machine and stored in the data base after they have been provided with a time stamp. \_(Example: the patient is sick and is administered 5 ml of medicine X.) Thus, all data of the treatment of the special patient are available in the system and describe the quality of the treatment. Confusing the patient and treatment data is impossible once the patient has been identified.

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- 6. The physician at the physician place 24 contemporarily sees the correlations between machine data, medication, and patient condition. He reacts with an instruction (e.g., another 5 ml of medicine X). This instruction directly appears at the machine at which the respective patient is located.
- 7. The instruction of the physician is obeyed, <u>and</u> the completion is again acknowledged by the nurse by inputting her ID code.\_ The physician directly receives a reply as to the execution.\_ The data are stored and can be processed further (e.g., repeat order of 10 ml of medicine X).

The personnel sees the respective instructions at the dialyzer. \_After the instruction has been executed and the acknowledgment has been performed at the video terminal, it transmits the acknowledgment to the server 20 on which the success of the job instruction is stored and can be shown for subsequent examinations. \_Moreover, the personnel is able to input measures performed without job instruction at the video terminal 16, which are also transmitted to the server 20 either with or without identification. \_Furthermore, it is possible to input occurrences appearing during the treatment, e.g., a drop of blood pressure, which are then transmitted to the central computer.

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It is advantageous that only the data for the treatment of the respective patient appear on the video terminal 16 of the patient place 10, that the personnel is able to input the protocol and remarks relating thereto directly at the dialyzer 12, that the attention of the personnel is drawn to instructions of the physician directly at the screen, and that the executions thereof are supervised.

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Although the invention has been described and illustrated with reference to specific illustrative embodiments thereof, it is not intended that the invention be limited to those illustrative embodiments. \_Those skilled in the art will recognize that variations and modifications can be made without departing from the true scope of the invention as defined by the claims that follow. \_It is therefore intended to include within the invention all such variations and modifications as fall within the scope of the appended claims and equivalents thereof.

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